

Number/Name: P-18-0030 / [REDACTED]

Updated 10-16-2018 with quantitative MOE calculations for workers and gen pop based on worst case analogue data identified by [REDACTED]

[REDACTED]. Changes below in red. Updates to summary bullets, PODs, and calculators only.

Updated 10/30/18 with new risk determination for irritation and sensitization to workers and PUI text

SUMMARY INFORMATION

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties, by comparing it to structurally analogous chemical substances for which there is information on human health hazard, and other structural information. EPA concludes there is low-to-moderate concern for human health hazard for the chemical substance.

Based on the hazard determination and available qualitative risk information, EPA concludes that there is risk for the PMN substance.

Human Health Hazard:

- Absorption of the low molecular weight fraction [REDACTED] is poor all routes, (pchem).
- Expect poor Michael addition to the [REDACTED]
- Concern for eye and skin irritation, mutagenicity, oncogenicity, developmental, liver, and kidney toxicities, and sensitization from the [REDACTED]
- While systemic concerns are somewhat mitigated by the high [REDACTED] FGEW (756) and negligible estimated water solubility (<0.000001 g/L), the LMW fraction comprises [REDACTED] of the PMN and the occupational exposures in particular were quite high. As such, worst case analogues ([REDACTED]) were used to conduct a quantitative assessment. These worst case analogues are not genotoxic *in vitro* and *in vivo* studies. Additionally, [REDACTED] is not considered carcinogenic and [REDACTED] was not carcinogenic to rats via inhalation exposure up to 773 mg/m³ (see [REDACTED]).
- No residual isocyanates reported.

Human Health Risk:

- Risks for irritation and sensitization to workers cannot be quantified due to a lack of dose-response for these hazards. However, exposures can be controlled by the use of appropriate

[REDACTED]

PPE, including impervious gloves and a respirator with an APF of 50 as described in the submitted SDS. EPA expects that workers will use appropriate personal protective equipment (i.e., impervious gloves, respirator), consistent with the Safety Data Sheet prepared by the PMN submitter, in a manner adequate to protect them. Therefore, EPA has not identified risks for the irritation and sensitization endpoints.

- Risks were *not* identified for workers for systemic effects via dermal contact based on worst case analogue data [REDACTED].
- Risks were *not* identified for workers for systemic effects via inhalation based on worst case analogue data [REDACTED].
- Risks were *not* identified for the general population for systemic effects via inhalation based on worst case analogue data [REDACTED].
- Risks were *not* identified for the general population for systemic effects via drinking water ingestion based on worst case analogue data [REDACTED] [REDACTED] [REDACTED] [REDACTED].
- Risks were not evaluated for consumers as consumer uses are not intended or reasonably foreseen.

Potentially Useful Information:

- Per the New Chemical Categories document, testing for acrylates/methacrylates is recommended on a case-by-case basis
- Potentially useful information would inform understanding of:
 - Genetic toxicology
- Additionally, Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test, would generate data to inform the concerns for developmental, liver, and kidney toxicities.

PART A

SAT Date: 31 October 2017

SAT Chair: Becky Daiss

Health Assessor: Amy Babcock

QC Reviewer: Susan Laessig, 11/6/17

Structure:

Max. PV (KG):	12000	Binding Option Marked:		Search Domain: All	^
MW:		% < 500	% < 1000	CASNO	1342283-42-4
PMN Structure	Prop.		Meas.	Est.	
	MP				
	BP			>500	
	Pres.			at 760 mm Hg	
	VP			<0.000001	
	S-H2O			<0.000001	
	log P				
USE:	Acrylate resin for UV-curable industrial coatings.		other_uses		

- CASRN: 1342283-42-4
- Chemical Category:
 - Acrylates/Methacrylates
- Chemical Category Health Concerns:
 - As a result of testing conducted under an agreement between the Agency and the Specialty Acrylates and Methacrylates (SAM) Panel of the Chemical Manufacturers Association (CMA), EPA no longer controls new chemical acrylates or methacrylates as a category based on health concerns. However, if a new acrylate is structurally similar to a substance for which EPA has positive toxicity data, EPA may regulate that substance under TSCA section 5(e) based on

[REDACTED]

its potential unreasonable risk. This will be done on a case-by-case basis and is expected to effectively eliminate most regulation of acrylates, especially higher molecular weight and polymeric substances. Despite the fact that EPA no longer expects to make a potential unreasonable risk to human health finding for many of the new acrylates, EPA still recommends the use of engineering controls or personal protective equipment to reduce exposures in the workplace in recognition of their potential as irritants and sensitizers.

- **Category Testing Strategy:**

- N/A

- **PMN Health Rating:**

- 1-2
- P3 B1 T2

- **SAT Key Words:**

- IRR-S; E; MUTA; ONCO; DEVEL; LIVER; KIDNEY; SENS

- **Absorption:**

- Absorption of the low molecular weight fraction [REDACTED] is poor all routes, based on physical/chemical properties.

- **SAT Health Summary:**

Expect poor Michael addition to the [REDACTED]. There are concerns for eye and skin irritation, mutagenicity, oncogenicity, developmental, liver, and kidney toxicities, and sensitization from the acrylate. No residual isocyanates reported.

- **PMN Data:** (study summary, POD)

- None submitted

- **Analog Data:** (analog, structure, study summary, POD)

- [REDACTED]
 - [REDACTED]

(38) ANALOGS:

PMN or CAS No.	Chem. Name	Structure	TSCA Y/N

- **Other Information: (structural alert or component of interest, basis, etc.)**
 - SDS

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit(s)

Permissible Exposure Limits (PELs): N.A

Threshold Limit Values (TLVs): N.A

Engineering Measures

Utilize a closed system process where feasible. Where this material is not used in a closed system, good enclosure and local exhaust ventilation should be provided to control exposure.

Respiratory Protection

Avoid breathing processing vapor or mist. Where airborne exposure is likely or airborne exposure limits are exceeded (if applicable, see above), use NIOSH approved respiratory protection equipment appropriate to the material and/or its components (full facepiece recommended). Consult respirator manufacturer to determine appropriate type equipment for a given application. For spray applications, a NIOSH certified respirator with an APF of 1000 is required. For all other means of application, a NIOSH certified respirator with an APF of 50 is required. Observe respirator use limitations specified by NIOSH or the manufacturer. For emergency and other conditions where there may be a potential for significant exposure or where exposure limit may be significantly exceeded, use an approved full face positive-pressure, self-contained breathing apparatus or positive-pressure airline with auxiliary self-contained air supply. Respiratory protection programs must comply with 29 CFR § 1910.134.

Eye Protection

Prevent eye and skin contact. Provide eye wash fountain and safety shower in close proximity to points of potential exposure. Wear eye/face protection such as chemical splash proof goggles or face shield.

Skin Protection

Prevent contamination of skin or clothing when removing protective equipment. Wear impermeable gloves and suitable protective clothing.

11. TOXICOLOGICAL INFORMATION

	Urethane acrylate	HPMA
Acute Toxicity Data		
Oral	No data	LD50 > 2000 mg/kg Rat
Dermal	No data	LD50 > 5000 mg/kg Rabbit
Inhalation	No data	No data
Skin Corrosion / Irritation	Irritating	Not irritating
Serious Eye Damage / Irritation	Irritating	Irritating
Respiratory Sensitization	No data	Guinea pig In animal experiments the substance shows low resp. no ability as a sensitizer.
Skin Sensitization	No data	There are indication of a sensitizing effect of the substance in man.
Carcinogenicity	No data	No data
Germ cell mutagenicity	No data	Negative
Reproductive toxicity	No data	No indication of toxic effects were observed in reproduction studies in animals.
Specific target organ toxicity	No data	No data
Aspiration hazard	No data	No data

- **Point of Departure Selected and Basis (WORST CASE ANALOGUES):**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Exposure Routes of Interest:

- ☐ Inhalation
- ☐ Dermal
- ☐ Ingestion

PART B

Focus Date: 09 November 2017

Focus Assessor: Amy Babcock

QC: Johanna Congleton

USES and EXPOSURES:

- **Uses:** Acrylate resin for UV-curable industrial coatings.
- **Worker Exposure:**
 - **Inhalation:** Exposure to Mist (non-volatile) Potential Dose Rate = 2.3E+1 mg/day
 - **Dermal:** Potential Dose Rate: 2.6E+3 mg/day (exposure to liquid at 30% concentration)
- **General Population Exposure:**
 - **Drinking Water:** 1.99E-03 mg/kg/d
 - **Fish:** Below modeling thresholds
 - **Air/Inhalation:** 1.80E-02 mg/kg/d (fugitive air)

Exposure Scenario ¹	Water						Landfill	Stack Air		Fugitive Air	
Release activity(ies) ² ; exposure calculation(s) ³	Drinking Water		Fish Ingestion		7Q10 ⁴	PDM Days Exceeded	LADD	ADR	LADD	ADR	LADD
	ADR	LADD	ADR	LADD	CC = 1000			(24-hr conc.)	(Annual conc.)	(24-hr conc.)	(Annual conc.)
	mg/kg/day	mg/kg/day	mg/kg/day	mg/kg/day	µg/l	# Days		mg/kg/day (µg/m ³)	mg/kg/day (µg/m ³)	mg/kg/day (µg/m ³)	mg/kg/day (µg/m ³)
PROC: Max ADR	1.99E-03	---	---	---	---	---	---	---	---	---	---
PROC: Max LADD	---	2.44E-06	---	---	---	---	---	---	---	---	---
USE: Max ADR	5.25E-04	---	---	---	---	---	---	---	---	1.80E-02 (9.84E+01)	---
USE: Max LADD	---	2.44E-06	---	---	---	---	---	---	---	---	4.17E-04 (5.39E+00)

- **Consumer Exposure:** Not expected due to no consumer uses

RISK CALCULATIONS:

- **Worker Calculations:**



Worker Risks via Inhalation; POD in mg/m ³							
MOE = Adj HEC / (Adj PDR); Benchmark (acceptable) MOE ≥100 or 1000							
Exposure Scenarios	POD ¹ HEC (mg/m ³)	Potential Dose Rate ² (mg/day)	8 hour exposure concentration ³ (mg/m ³)	Exposure Route Absorption Adj ⁴	Structural Alert/ Component as % of PMN	Margin of Exposure (POD/ PDR)	Inhalation Fold Factor (Benchmark/ MOE) ⁵
WORKER RISK							(NOAEL=100)
Highest/Worst Case Doses from Engineering Report							(LOAEL=1000)
Inhalation	84.4	23	2.3	15%	19%	1292.3	1
¹ POD is the Point of Departure derived from an animal study, and may be a LOAEL or NOAEL. HEC is the Human Equivalent Concentration adjusted from the animal POD based on exposure duration. ² Inhalation doses in mg/day are from the Engineering Report generated using ChemSTEER. Unless otherwise stated, the assumption is an 8-hr day. ³ PDR in mg/day is converted to an exposure concentration mg/m ³ using this formula: mg/m ³ = (mg/day) / (8 hrs/day x 1.25 m ³ /hr). The breathing rate used in the exposure assessment for humans is 1.25 m ³ /hour S ⁴ Absorption adjustments for Focus: Assume 100% POD; if risks, consider adjusting for absorption, etc. ⁵ Fold factor = value to be applied to bring INHALATION MOE up to acceptable level, used by the Industrial Hygienist to determine respirator recommendations. NOAEL-based fold factor = 100/MOE; LOAEL-based fold factor = 1000/MOE.							

Focus Worker Calculations MOE = (POD x Abs Rate) / ((PDR x Abs Rate) / BW) Acceptable MOE ≥100									
Exposure Scenarios and Values	POD= NOAEL (mg/kg/ day)	POD Route Absorp Adj ¹		Potential Dose Rate (mg/day)	Exposure Route Absorp Adj ²	Structural Alert/ Component as % of PMN	Avg BW ³ All Adults, 80 (kg)		Margin of Exposure ⁴ (POD/PMN Dose)
WORKER RISK									
Highest/Worst Case Doses from Engineering Report									
Dermal	(1081	x 100%) ÷	(2.60E+03	x 15%	x 19%	÷ 80) =	1171.3872
¹ Absorption adjustments for Focus - Assume 100% for POD; For Exposure. If risks, consider adjustments for absorption,etc. ³ USEPA 2011. Exposure factors handbook, final report, EPA/600-R09/052F, 2011, Chapter 8 Body Weight Studies,Table 8-1, Recommended Values for Body Weight http://www.epa.gov/ncea/efh/pdfs/efh-chapter08.pdf ⁴ Benchmark (Acceptable) MOEs are 100 for NOAEL-based assessment and 1000 for LOAEL-based assessment									

- General Population Calculations:



Focus General Population and Consumer MOE Calculations MOE = (POD x Abs Rate) / ((PDR x Abs Rate) / BW) Benchmark (acceptable) MOE ≥100												
Exposure Scenarios and Values ¹	POD= NOAEL (mg/kg/day)		POD Route Absorp Adj ²		Exposure Acute Dose Rate (mg/kg/day)		Exposure Route Absorp Adj ²		Multiplier for Sensitive Sub-populations ⁴		Structural Alert/ Component as % of PMN	Margin of Exposure (POD/PMN Dose)
GENERAL POPULATION RISK												(NOAEL=100)
Highest/Worst Case Doses from Exposure Report												
Drinking Water	(111	x	100%) ÷ (1.99E-03	x	15%	x	1.00	x	19%) = 1964391
Drinking Water	(111	x	100%) ÷ (1.99E-03	x	15%	x	4.17	x	19%) = 471077
¹ General Population and Consumer ingestion Acute Dose Rates are from the Exposure Report and are generated using E-FAST which assumes a 100% absorption rate, and uses an average adult body weight of 80 kg. Consumer ADRs are generated using the Consumer Exposure Module within the E-FAST CBI version called "NCEM2" model.												
² Absorption adjustments for Focus: Assume 100% POD; if risks, consider adjusting for absorption, etc.												
³ Benchmark (Acceptable) MOEs are 100 for NOAEL-based assessment and 1000 for LOAEL-based assessment												
⁴ Multiplier based on increased drinking water consumption for infants. Multiplier would be less for older populations, so this value is worst-case.												

General Population Risks via Inhalation; HEC in µg/m ³ MOE = Adj HEC / (ADR); Benchmark (acceptable) MOE ≥100 or 1000					
Exposure Scenarios	HEC ¹ (µg/m ³)	Acute Dose Rate ² (µg/m ³)	Exposure Route Absorption Adj ³	Structural Alert/ Component as % of PMN	Margin of Exposure (HEC/ ADR)
GENERAL POPULATION RISK					
Highest/Worst Case Doses from Exposure Report					
Inhal. (fugitive)	40178.0	9.8E-01	15%	19%	1437975
¹ HEC is the Human Equivalent Concentration adjusted from the animal POD based on exposure duration.					
² Inhalation doses in µg/m ³ are from the Exposure Report generated using EFast. Unless otherwise stated, the assumption is an 24-hr day.					
³ Absorption adjustments for Focus: Assume 100% POD; if risks, consider adjusting for absorption, etc.					

- **Consumer Calculations:** Risk was not assessed because consumer exposures are not expected.